UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,105	10/25/2005	Takafumi Ishii	62936 (46342)	2820

21874 7590 06/03/2009

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
06/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,105	ISHII ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,21,24,25,28,29,31,32,37-40,42,43,46 and 47* is/are pending in the application.

4a) Of the above claim(s) *1-3,10,11,14,21,24,28,29,31,32,37-40,42,46- 47* is/are withdrawn from consideration.

5)☒ Claim(s) *6 and 7* is/are allowed.

6)☒ Claim(s) *4,5,8,9,12,13,25 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence, Tang etal* .

Request for Continued Examination

The request filed on 2/13/2009 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10525105 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 15-20, 22-23, 26-27, 30, 33-36, 41, 44-45, are 48-50 are cancelled.

Claims 1-14, 21, 24-25, 28-29, 31-32, 37-40, 42-43, 46-47 are pending.

Claims 1-3, 10-11, 14, 21, 24, 28, 29, 31-32, 37-40, 42, 46-47 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species.

Claims 4-9, 12-13, 25, and 43, drawn to polynucleotides (DNA), a kit and composition, vector, transformant thereof to the extent of SEQ ID NO: 16, are under considerations

Conclusion from previous final Office Action dated 10/15/2008

Claim 7 is allowed.

Claim 6 is objected to as being dependent upon the rejected claims 5.

Claims 4-5, 8-9, 12-13, 25, and 43 are rejected.

Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-5, 8-9, 12-13, 25, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides of SEQ IDN O:16 and the vector, the transformant, the pharmaceutical composition , and the diagnosing kit comprising the polynucleotides of SEQ IDN O:16, does not reasonably provide enablement for its variant having at least 95% homology to the polynucleotide of SEQ ID NO: 16, The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The instant claims are broadly drawn to an isolated polynucleotide, vector, transformant, composition or kit comprising the polynucleotide, wherein the polynucleotide is at least 95% homology to the sequence of SEQ ID NO: 16. The SEQ ID NO: 16 contains 3072 nucleic acids. Up to 5% difference in the sequence would include up to 153 nucleic acid mutation(s), deletion(s), addition(s), which could be any length up to 153 nucleic acids and located anywhere in the sequence. Thus, the claimed polynucleotides are inclusive of a genus of widely ranged variants to the nucleotides of SEQ ID NO: 16.

To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. The specification first teaches that the differential expression of the gene FLJ20539 (Genbank accession No: AK000546) is found in human gastric cancer and other human cancers (page 1, and example 1). Using the primers from the gene FLJ20539, the high homologous TACT427-A cDNA (SEQ ID NO: 16) is cloned from human brain cDNA library (example 4). The specification then teaches that the enhanced expressions of both FLJ20539 and TACT427A genes are found in many cancer tissues and cell lines (example 1 and examples 8+). The specification although discloses a few homologous clones of TACT427-A (SEQ ID NO: 16, 3072 nts) having longer (SEQ ID NO: 19, 3505 nts) or short nucleotide sequence (SEQ ID NO: 18, 3060 nts), both SEQ ID NO: 19 and 18 are 100% local match and only difference is the length (see SCORE in published application database). The specification teaches neither the substitutions, mutations, deletions, additions anywhere up to 5% of the nucleic acids of

SEQ ID NO: 16, nor the expression of those genes in cancer cells or tissues. As such, one skilled in the art would not know how to make the claimed variants of SEQ ID NO: 16 and therefore would not know how to use the variant for detecting the expression in a tumor, diagnosing, or treating a tumor condition.

The sequence of SEQ ID NO: 16 (3072 nts) is free of the art, but the homologs with high sequence identity (up to 99% identity) to the polynucleotide of SEQ ID NO: 16 are found in those known genes. However, the differential expressions of those homologs have not been found to be related with the cancer conditions. For example, Belouchi et al., in the post filing PCT application (WO2006116867-SEQ ID NO: 546, 3520 nts) teach a Crohns disease related polynucleotide having more than 99% sequence identity to the polynucleotide of SEQ ID NO: 16. Belouchi et al., teach that the expression of the gene is susceptibility to Crohn's diseases (sequence is provided 10/2008). Accordingly, one skilled artisans have recognized that the expression of the homologs of the nucleotides of SEQ ID NO: 16 may or may not be involved in a cancer condition. The relationship between the variously pathological conditions and expressions of the variants of SEQ ID NO: 16 are not predictable and undue experimentations are required for one skilled in the art to make (or find) a variant with up to 5% sequence difference from SEQ ID NO: 16 in the cancer conditions and determine whether it has a contribution for the cancer development or exclusively expressed in a cancer condition, which could be used for the cancer detection.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification dose not provide objective evidence for claimed

homologs at least 95% identity to TACT427-A (SEQ ID NO: 16) or composition and kit comprising thereof as what has been disclosed for the function and expression of TACT427-A (SEQ ID NO: 16. Thus, in view of the lack of predictability of the prior art, the breadth of the claims, the lack of guidance and support in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

At page 10 of the remarks filed with the amendment, Applicant states that the claimed polynucleotide has amended from 80% to 95% homology to the SEQ ID NO: 16, one skilled in the art could readily make and use the homology polynucleotide, vector, transformant, composition, or kit. This has been carefully considered but is deemed not to be persuasive as the reasons set forth in the rejection above.

Conclusion

Claims 6 and 7 are free or art and allowed.

Claims 4-5, 8-9, 12-13, 25, and 43 are rejected.

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Tang et al (US 20080050393, SEQ ID NO: 144489, priority to 2001) disclose a polynucleotide (cDNA) having 6379 nucleic acids, in which the nucleic acids from 2258 to 5362 are 93.3% query match and 96.6% local match to the SEQ ID NO: 16 with an insertion at 5' end (see attached). Tang et al do not teach or suggest a polynucleotide

comprising a polynucleotide having more than 95% sequence identity to the entire sequence of SEQ ID NO: 16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao/
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643